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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Balbierz, et al.

Group No.: 3736

Serial No.: 09/823,903

Examiner: NA

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For: Tissue Biopsy Treatment Apparatus
and Method

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Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir or Madame:

Prior to the examination of the above-identified patent application on the merits, please consider the following amendments and remarks.

In the Claims:

1. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

2. (Amended) The apparatus of claim 1, wherein the plurality of resilient members includes a first resilient member, a second resilient member and a third resilient member.

8. (Amended) The apparatus of claim 6, wherein the logic resources are configured to distinguish between at least one of necrosed and non-necrosed tissue, necrosed and non-necrosed healthy tissue or necrosed and non-necrosed abnormal tissue, non-necrosed healthy tissue and necrosed abnormal tissue.

11. (Amended) The apparatus of claim 10, wherein the logic resources are configured to graphically display on the display device the position of the energy delivery device relative to the tumor mass or the ablation volume.

13. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site;

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device; and

logic resources coupled to one of the sensor array, the sensor, the energy delivery device or a power source coupled to the energy delivery device, the logic resources including a processor, the logic resources configured to identify or differentiate tissue responsive to a signal from one of the sensor or the sensor array.

14. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample and measure a spectral profile of at least one portion of a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

15. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being

positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to substantially simultaneously sample tissue in multiple tissue volumes of a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

16. (Amended) A tissue biopsy and treatment apparatus for detecting and treating a tumor, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site and detect one of a boundary or a volume of a tumor as at least a portion of the sensor array is advanced into the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

17. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a non deployed state and being deployable from the elongated delivery device into tissue with a changing direction of travel responsive to tissue applied forces, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

20. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site during an energy delivery interval, a tissue desiccation condition, a tissue charring condition or a tissue vaporization condition; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

27. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members being maneuverable in tissue, at least one of the plurality of resilient members including a lumen and an optical sensor member positionable within the lumen; the sensor array having a geometric configuration adapted to volumetrically sample at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

32. (Amended) The apparatus of claim 31, wherein the indicator of cell necrosis is a tissue vapor bubble, a rate of tissue vapor bubble formation, a denatured tissue protein, a denatured DNA or an intracellular fluid.

35. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array configured to volumetrically sample tissue at a tissue site and distinguish between healthy tissue and abnormal tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

40. (Amended) The apparatus of claim 38, wherein the first sensor comprises a first optical member positionable within a lumen of a first resilient member of the plurality of resilient members and the second sensor is a second optical member positionable within a lumen of a second resilient member of the plurality of resilient members.

42. (Amended) The apparatus of claim 38, wherein at least one of the first or the second sensors is an emitter, an electromagnetic emitter, an optical emitter, an acoustical emitter, a laser or an LED.

46. (Amended) The apparatus of claim 45, wherein the sensor includes a third sensor adapted to detect the reference signal.

48. (Amended) The apparatus of claim 47, wherein the third sensor is positioned substantially adjacent or in proximity to the emitter.

54. (Amended) The apparatus of claim 52, wherein the sensor array is configured to obtain one of an improved resolution or an improved sensitivity.

62. (Amended) The apparatus of claim 60, wherein the plurality of marking agents include a first marking agent configured to mark a first tissue condition or first tissue type and a second marking agent configured to mark a second tissue condition or a second tissue type.

67. (Amended) The apparatus of claim 66, wherein the second tissue temperature is one of a tissue injuring temperature, a tissue necrosing temperature, a tissue ablative temperature, or a tissue vaporization temperature.

69. (Amended) The apparatus of claim 60, wherein the plurality of marking agents includes a first marking agent coupled to a first marking agent carrier, wherein the first marking agent carrier is configured to release the first marking agent at a selectable temperature, tissue condition or tissue chemical concentration.

72. (Amended) The apparatus of claim 69, wherein the plurality of marking agents includes a second marking agent coupled to a second marking agent carrier, wherein the second marking agent carrier is configured to release the first marking agent at a selectable temperature.

79. (Amended) The apparatus of claim 77, further comprising:
a handpiece coupled to one of the elongated delivery device or the sensor array; and
a first advancement device at least partially positionable in one of the handpiece or the elongated delivery device, the advancement device configured to advance at least one of the plurality of resilient members or the sensor.

80. (Amended) The apparatus of claim 79, further comprising:
a second advancement device at least partially positionable in one of the handpiece or the elongated delivery device, the second advancement device configured to advance at least one of the plurality of resilient members or the sensor independent of an advancement of the first advancement device.

81. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of deployable RF electrodes, at least one of the plurality of RF electrodes being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of RF electrodes including at least one of a tissue piercing distal end, an electrode lumen or at least one optical sensor member positionable in the electrode lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site;

a handpiece coupled to one of the elongated delivery device or the sensor array; and

a rigid advancement device at least partially positionable in the handpiece, the advancement device configured to advance at least one of the plurality of RF electrodes or the at least one optical sensor member.

82. (Amended) A tissue biopsy and treatment apparatus for detecting and treating a tissue site, the apparatus comprising:

an elongated delivery device means including a lumen means;

a sensor array means including a plurality of resilient member means, at least one of the plurality of resilient member means being positionable in the elongated delivery device means in a compacted state and deployable from the elongated delivery device means with curvature in a deployed state, at least one of the plurality of resilient member means including at least one of a sensor means or a tissue piercing distal end means, the sensor array means having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device means coupled to one of the sensor array means, at least one of the resilient member means or the elongated delivery device means.



CONCLUSION

Applicant submits that the present application is in form for allowance, and such action is respectfully requested. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No 50-1865 (Docket No. 13724-844).

Respectfully submitted,

Rita Medical Systems Inc.

By: _____

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1.(Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

2.(Amended) The apparatus of claim 1, wherein the plurality of resilient members includes a first resilient member, a second resilient member and a third resilient member.

8.(Amended) The apparatus of claim 6, wherein the logic resources are configured to distinguish between at least one of necrosed and non-necrosed tissue, necrosed and non-necrosed healthy tissue or necrosed and non-necrosed abnormal tissue, [or] non-necrosed healthy tissue and necrosed abnormal tissue.

11.(Amended) The apparatus of claim 10, wherein the logic resources are configured to graphically display on the display device the position of the energy delivery device relative to the tumor mass or the ablation volume.

13.(Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being

positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site;

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device; and

logic resources coupled to one of the sensor array, the sensor, the energy delivery device or a power source coupled to the energy delivery device, the logic resources including a processor, the logic resources configured to identify or differentiate tissue responsive to a signal from one of the sensor or the sensor array.

14.(Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample and measure a spectral profile of at least one portion of a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

15.(Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of

resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to substantially simultaneously sample tissue in multiple tissue volumes of a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

16.(Amended)A tissue biopsy and treatment apparatus for detecting and treating a tumor, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site and detect one of a boundary or a volume of a tumor as at least a portion of the sensor array is advanced into the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

17.(Amended)A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a non deployed state and being deployable from the elongated delivery device into tissue with a changing direction of travel responsive to tissue applied forces, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

20.(Amended)A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member] delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site during an energy delivery interval, a tissue desiccation condition, a tissue charring condition or a tissue vaporization condition; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

27.(Amended)A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member] delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members being maneuverable in tissue, at least one of the plurality of resilient members including a lumen and an optical sensor member positionable within the lumen; the sensor array having a geometric configuration adapted to volumetrically sample at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

32.(Amended)The apparatus of claim 31, wherein the indicator of cell necrosis is a tissue vapor bubble, a rate of tissue vapor bubble[s] formation, a denatured tissue protein, a denatured DNA or an intracellular fluid.

35.(Amended)A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array configured to volumetrically sample tissue at a tissue site and distinguish between healthy tissue and abnormal tissue at the tissue site; and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device.

40.(Amended)The apparatus of claim [39]38, wherein the first sensor comprises a first optical member positionable within a lumen of a first resilient member of the plurality of resilient members and the second sensor is a second optical member positionable within a lumen of a second resilient member of the plurality of resilient members.

42.(Amended) The apparatus of claim 38, wherein at least one of the first or the second sensors is an emitter, an electromagnetic emitter, an optical emitter, an acoustical emitter, a laser or an LED.

46.(Amended) The apparatus of claim [42]45, wherein the sensor includes a third sensor adapted to detect the reference signal.

48.(Amended) The apparatus of claim 47, wherein the third sensor is positioned substantially adjacent or in proximity to the emitter.

54.(Amended)The apparatus of claim 52, wherein the sensor array is configured to obtain one of an improved resolution or an improved sensitivity.

62.(Amended) The apparatus of claim 60, wherein the plurality of marking agents include a first marking agent configured to mark a first tissue condition or first tissue type and a second marking agent configured to mark a second tissue condition or a second tissue type.

67.(Amended) The apparatus of claim 66, wherein the second tissue temperature is one of a tissue injuring temperature, a tissue necrosing temperature, a tissue ablative temperature, or a tissue [a] vaporization temperature.

69.(Amended) The apparatus of claim 60, wherein the plurality of marking agents includes a first marking agent coupled to a first marking agent carrier, wherein the first marking agent carrier is configured to release the first marking agent at a selectable temperature, tissue condition or tissue chemical concentration.

72.(Amended) The apparatus of claim 69, wherein the plurality of marking agents includes a second marking agent coupled to a second marking agent carrier, wherein the second marking agent carrier is configured to release the first marking agent at a selectable temperature.

79.(Amended) The apparatus of claim 77, further comprising:
a handpiece coupled to one of the elongated delivery device or the sensor array; and
a first advancement device at least partially positionable in one of the handpiece or the elongated [member]delivery device, the advancement device configured to advance at least one of the plurality of resilient members or the sensor.

80.(Amended)The apparatus of claim 79, further comprising:
a second advancement device at least partially positionable in one of the handpiece or the elongated [member]delivery device, the second advancement device configured to advance at least one of the plurality of resilient members or the sensor independent of an advancement of the first advancement device.

81.(Amended)A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated [member]delivery device, the sensor array

including a plurality of deployable RF electrodes, at least one of the plurality of RF electrodes being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of RF electrodes including at least one of a tissue piercing distal end, an electrode lumen or at least one optical sensor member positionable in the electrode lumen[;], the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site;

a handpiece coupled to one of the elongated delivery device or the sensor array; and

a rigid advancement device at least partially positionable in the handpiece, the advancement device configured to advance at least one of the plurality of RF electrodes or the at least one optical sensor member.

82.(Amended)A tissue biopsy and treatment apparatus for detecting and treating a tissue site, the apparatus comprising:

an elongated delivery device means including a lumen means;

a sensor array means including a plurality of resilient member means, at least one of the plurality of resilient member means being positionable in the elongated delivery device means in a compacted state and deployable from the elongated delivery device means with curvature in a deployed state, at least one of the plurality of resilient member means including at least one of a sensor means, [a lumen means,] or a tissue piercing distal end means, the sensor array means having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and

at least one energy delivery device means coupled to one of the sensor array means, at least one of the resilient member means or the elongated delivery device means.

